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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

KAISER FOUNDATION HEALTH PLAN INC.,

Plaintiff,

vs.

ABBOTT LABORATORIES,

Defendant.

CASE NO. CV-02-02443-JFW (FMOx)

ABBOTT'S [PROPOSED] STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

Hearing Date: October 5, 2009
Hearing Time: 1:30 PM
Room: Ctrm. #16
Pretrial Conf.: January 8, 2010
Trial: January 26, 2010

Judge: Hon. John F. Walter

After consideration of the papers in support of and in opposition to Defendant Abbott Laboratories' Motion for Summary Judgment and the oral argument of counsel, the Court hereby finds that there is no genuine dispute as to the following facts and concludes that the following conclusions of law correctly state the applicable law and that Abbott is entitled to summary judgment as a matter of law. Now therefore, this Court hereby makes and enters its findings of uncontroverted facts and conclusions of law, as stated below.

I. UNCONTROVERTED FACTS

A. PROCEDURAL HISTORY

Uncontroverted Fact	Supporting Evidence
1. Kaiser filed its Complaint on March 22, 2002.	Declaration of Rohit K. Singla ("Singla Decl.") Ex. D [Complaint].
2. The Complaint alleged that (1) patent settlement agreements between Abbott and two generic companies violated Section 1 of the Sherman Act, and (2) Abbott's allegedly sham patent litigation on a number of patents violated Section 2 of the Sherman Act.	Singla Decl. Ex. D [Complaint].
3. In September 2002, the Judicial Panel on Multidistrict Litigation ordered this case transferred to the Southern District of Florida for pretrial proceedings.	Docket #19.
4. The Florida court granted partial summary judgment in favor of various plaintiffs on their Section 1 claims, but that ruling was reversed by the Eleventh Circuit on interlocutory appeal on September 15, 2003.	*Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1313 (11th Cir. 2003)
5. The Florida court then ordered each plaintiff to file a "Bill of Particulars" that would detail the claims that the particular plaintiff proposed to	Singla Decl. Ex. G [MDL Order regarding "Bill of Particulars"].

pursue in light of the Eleventh Circuit's ruling.	
6. Kaiser filed its Bill of Particulars on October 27, 2003, asserting a *Walker Process* claim for the first time.	Singla Decl. Ex. H [Kaiser's "Bill of Particulars"] at 4-5.
7. Abbott sought summary judgment on the sham litigation and *Walker Process* claims, arguing that those claims failed on the merits and were time-barred. Kaiser filed a partial summary judgment motion alleging that Abbott had monopoly power as a matter of law.	Singla Decl. Ex. N [August 31, 2004 Sum. J. Ruling] at 1-2, 49-50; Singla Decl. Ex. F.
8. On August 31, 2004, the Florida court granted summary judgment to Abbott on Kaiser's claims under Section 2 of the Sherman Act, including on Kaiser's *Walker Process* claim.	Singla Decl. Ex. N [August 31, 2004 Sum. J. Ruling] at 1-2, 49-50.
9. Because the Florida court ruled for Abbott on the Section 2 claims on other grounds, it did not reach the statute of limitations or the issue of monopoly power.	Singla Decl. Ex. N [August 31, 2004 Sum. J. Ruling] at 49-50.
10. The case then returned to this Court for trial on Kaiser's Section 1 claim.	Docket # 22
11. After a jury verdict in Abbott's favor, judgment was entered for Abbott on April 6, 2006.	Docket # 204.
12. On appeal, the Ninth Circuit affirmed judgment for Abbott on the Section 1 claims and on the sham litigation Section 2 claims.	*Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1053 (9th Cir. 2009).
13. The Ninth Circuit reversed the Florida court's summary judgment ruling on Kaiser's *Walker Process* claim, however, and remanded to this	*Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1053 (9th Cir. 2009).

court for further proceedings.	
14. The Ninth Circuit declined to rule on Abbott's statute of limitations defense, instead stating that the question could be presented to this Court on remand.	*Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1053 (9th Cir. 2009).
15. As part of the MDL proceedings, the parties stipulated to much of the factual record on which summary judgment was decided.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute]. [1]

B. BACKGROUND ON KAISER'S *WALKER PROCESS* CLAIM

16. Abbott developed and manufactures the branded drug Hytrin®.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 165, 173.
17. Hytrin treats hypertension and enlargement of the prostate.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 173; *see also* Declaration of Mark Soloway ("Soloway Decl.") Ex. A [Soloway Report] at 4-10.
18. Hytrin's active ingredient is terazosin hydrochloride.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 166.
19. Abbott has received a number of patents covering terazosin hydrochloride, its pharmaceutical use, and its crystalline forms.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 41-50.
20. Abbott is the assignee of Patent 5,504,207 ("the '207 patent"), which claims a crystalline form of terazosin hydrochloride called Form IV.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 49.

[1] As part of the original summary judgment proceedings, the MDL district court ordered the parties to present a detailed Joint Statement of Facts Not in Dispute. Abbott's proposed statement of uncontroverted facts relies on these facts, stipulated for purposes of summary judgment, for most of the critical facts.

21. Kaiser has alleged that, in prosecuting the '207 patent, Abbott's patent attorney intentionally failed to submit a translation of the Japanese "Sumika" reference and failed to disclose a Federal Circuit decision purportedly contrary to Abbott's legal arguments regarding the application of the on-sale bar to the '207 patent.	Singla Decl. Ex. H [Kaiser's Bill of Particulars] at 4-5; Singla Decl. Ex. B [Kaiser's opening brief in appeal to Ninth Circuit] at 27-32.
22. The Japanese original of the Sumika reference was submitted in the '207 prosecution.	Singla Decl. Ex. E [Application for the '207 Patent]
23. The English translation of the Sumika reference was submitted in a closely related application (for the '095 patent) pending before the same primary examiner.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 134, 135, 139, 140.

C. FACTS RELATING TO ABBOTT'S STATUTE OF LIMITATIONS DEFENSES

1. Kaiser First Pled A *Walker Process* Claim In October 2003.

Uncontroverted Fact	Supporting Evidence
24. Kaiser's Complaint said nothing about the prosecution of the '207 patent. It did not describe the materials submitted during the prosecution of the '207 patent, Abbott's or its prosecuting attorney's intent during the prosecution, the materials that the Examiner reviewed, or the process of prosecuting the patent application. And it did not allege fraud in the '207 application.	Singla Decl. Ex. D [Complaint].
25. Kaiser's Complaint did not allege the omission of the translation of the Sumika reference or the failure to cite a Federal Circuit case relating to the on-sale bar.	Singla Decl. Ex. D [Complaint].

26. In support of its sham litigation claim, Kaiser's Complaint alleged that Abbott had "listed with the FDA several new patents and inaccurate information relating to these patents" and then filed "frivolous" litigation based on these listings in order to delay entry into the market by generic competitors.	Singla Decl. Ex. D [Complaint] ¶¶ 76-77.
27. [NOT USED]	
28. In its Bill of Particulars, filed October 27, 2003, Kaiser asserted that during the '207 patent prosecution, Abbott intentionally omitted the "the English translation of a material prior art foreign patent" and "misrepresent[ed] . . . the law on the on-sale bar" and that "the patent would not have issued but for [these] misrepresentation[s] and omissions."	Singla Decl. Ex. H [Kaiser's "Bill of Particulars"] at 4-5.
29. Abbott objected to the plaintiffs' using their "Bills of Particulars" to amend their Complaints and specifically requested that Kaiser be required to formally amend its Complaint to reflect any new claims.	Singla Decl. Ex. I [Abbott's Response to Kaiser's "Bills of Particulars"] at 16 n.2.

2. **According to Kaiser's Allegations, All of Abbott's Purportedly Wrongful Conduct Took Place More Than Four Years Before Kaiser Asserted Its Walker Process Claim.**

30. Abbott filed the application for the '207 patent on October 18, 1994.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 49.
31. The '207 patent issued on April 2, 1996.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 49.
32. Abbott listed the '207 patent in the so-called "Orange Book" in April	Singla Decl. Ex. A [Joint Statement of

1996, thereby, under the Hatch-Waxman Act, requiring generic applicants to "certify" to the patent and staying approval of the generic applicants against whom Abbott timely asserted the '207 patent.	Facts Not in Dispute] ¶¶ 6-14, 107.
33. On June 4, 1996, Abbott filed suit against Geneva Pharmaceuticals, Inc. ("Geneva") for infringement of the '207 patent with respect to Geneva's tablet product.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 109.
34. On September 13, 1996, Abbott filed suit against Novopharm for infringement of the '207 patent. This case was consolidated with the Geneva '207 suit.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 112.
35. On October 28, 1997, Abbott sued Invamed for infringement of the '207 patent. This case was consolidated with the Geneva and Novopharm '207 suits.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 117.
36. On August 7, 1997, Abbott sued Mylan for infringement of the '207 patent.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 124.
37. On March 2, 2008, Abbott brought a second infringement suit against Mylan with respect to an additional dosage strength of terazosin.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 127.
38. Invamed and Mylan could not have come to market before Geneva.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 9, 13, 34, 143, 160.
39. Invamed never came to market with a terazosin product even after all the litigation was complete.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 34, 35.
40. Abbott sued generic drug company Warner on April 6, 1998.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 130.

41. Warner never obtained tentative or final FDA approvals for terazosin products.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 38.

3. **Kaiser's Alleged Injury Occurred More Than Four Years Before Kaiser Asserted Its Walker Process Claim.**

42. Under the Hatch-Waxman Act, the FDA issues tentative approval to a generic drug when it finds the generic drug application ("ANDA") would receive final FDA approval but for a stay resulting from Hatch-Waxman patent litigation.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 14.
43. Novapharm received tentative approval for terazosin tablets on November 26, 1996.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 31.
44. Geneva received tentative approval for terazosin tablets on June 17, 1997.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 29.
45. All of the lawsuits enforcing Abbott's terazosin patents (other than the '207 patent), and the stays on final FDA marketing approval that were triggered by those lawsuits, had ended by January 14, 1997.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 51-106.
46. Kaiser has alleged that "by 1996, generic manufacturers could and would have begun marketing a generic version of Hytrin but for Abbott's unlawful efforts to extend its patent monopoly."	Singla Decl. Ex. D [Complaint] ¶ 60, 98.
47. Kaiser contends that its Section 2 damages began in 1996, "the date that Kaiser contends that a generic competitor would have begun	Singla Decl. Ex. J [Berndt Report] ¶ 87.1.

marketing a generic version of Hytrin if Abbott had not engaged in improper efforts to prevent such entry."	
48. On July 1, 1999, the Federal Circuit affirmed summary judgment against Abbott in the Geneva, Novopharm and Invamed '207 patent litigation.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 119, 122.
49. The Federal Circuit denied rehearing on August 6, 1999, and the court's mandate issued on August 12, 1999.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 122.
50. By August 13, 1999, the 30-month regulatory stay triggered by the Geneva '207 suit had ended.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶¶ 12; 15, 122.
51. Geneva launched its generic terazosin product on August 13, 1999.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 187.
52. Kaiser admits it cannot recover for damages incurred more than four years before assertion of the claim.	Singla Decl. Ex. C [Kaiser's Response to Defendants' Motion for Summary Judgment on Sherman Act Section 2 (and Analogous) Claims] at 18 ("What the four-year statute does . . . is not to bar the lawsuit, but to limit the damages that can be recovered.").
53. By October 27, 1999, Kaiser had begun purchasing generic terazosin from Geneva and had stopped purchasing from Abbott.	Singla Decl. Ex. J [Berndt Report] at Tab 8, page 3.

4. **Kaiser Had Notice of the Alleged Wrongdoing in 1996.**

54. The PTO patent file on the '207 application was public record after the patent issued in April 1996.	37 C.F.R. § 1.11(a) (1996) ("After a patent has been issued or a statutory invention registration has been published, the specification, drawings and all papers relating to the case in the file of the patent or statutory invention

	registration are open to inspection by the public, and copies may be obtained upon paying the fee therefor.").
55. In June 1996, Geneva filed a public Answer in the '207 patent litigation.	Declaration of Tina Tabacchi ("Tabacchi Decl.") Ex. A [Geneva Answer] at 18.
56. Geneva's Answer stated: "Abbott's attorney mischaracterized the legal authorities on which he relied, and failed to disclose legal authorities" relating to Geneva's on-sale bar assertion and "submitted an English-language abstract of the Sumika application . . . [but not] an English translation of the Sumika application itself."	Tabacchi Decl. Ex. A [Geneva Answer] at ¶¶ 33, 39, 41.
57. Kaiser followed Abbott's patent litigation against potential Hytrin competitors and talked to Geneva about that litigation.	Singla Decl. Ex. K [Kramer Depo.] at 78:18-80:4; 207:7-208:14.

D. FACTS RELATING TO KAISER'S LACK OF ANTITRUST STANDING.

58. In the '207 patent infringement litigation, Geneva and Novopharm initially pursued accusations relating to the allegedly omitted translation of the Sumika reference.	Tabacchi Decl. Ex. A [Geneva Answer] at ¶¶ 33, 39, 41; Tabacchi Decl. Ex. B [Wong Depo.] at 16:3-17:8.
59. Counsel for Novopharm in the '207 patent infringement litigation deposed the patent examiner on the '207 patent application with respect to his consideration of the Sumika reference.	Tabacchi Decl. Ex. B [Wong Depo.] at 10:22-17:9.
60. Counsel for Novopharm terminated the deposition of the patent examiner after less than an hour—after the patent examiner testified, inter alia,	Tabacchi Decl. Ex. B [Wong Depo.] at 1:1-17:09, 17:17.

that, in reviewing the '207 patent application, he had read portions of the Sumika patent in the original Japanese and that he had the English translation available to him in another related file.	
61. After the deposition of the patent examiner, Geneva and Novopharm did not further pursue allegations that Abbott had failed to include a translation of the Sumika patent in the '207 patent application.	Tabacchi Decl. ¶ 4.

E. FACTS RELATING TO ABBOTT'S LACK OF MONOPOLY POWER

1. The "Relevant Market" Should Not Be Limited to Hytrin And Generic Terazosin

62. Hytrin belongs to a group of drugs known as "alpha-blockers."	Singla Decl. Ex. D [Complaint] ¶ 57.
63. In addition to Hytrin and generic terazosin, the "alpha-blockers" include Cardura (generically, doxazosin), Minipress (generically, prazosin), and Flomax (generically, tamsulosin).	Singla Decl. Ex. L [Millares Depo.] at 96:12-97:23; Declaration of James Langenfeld ("Langenfeld Decl.") Ex. A [March 22, 2002 Langenfeld Report] at 39, 43-47; Soloway Decl. Ex. A [Soloway Report] at 12-14.
64. Each of these alpha-blockers—Cardura (generically, doxazosin), Minipress (generically, prazosin), and Flomax (generically, tamsulosin)—do much the same thing in much the same way.	Soloway Decl. Ex. A [Soloway Report] at 12-14.
65. Hytrin is reasonably interchangeable with other alpha-blockers—including generic terazosin, Cardura, Minipress, and Flomax—as well as with Proscar.	Singla Decl. Ex. L [8/21/03 Millares Depo.] at 115:8-116:2; Singla Decl. Ex. Q [Soloway Depo.] at 11:7-18:3, 16:13-20, 23:9-25, 49:21-50:18, 53:12-19.
65A. As Prof. Berndt has himself written, pharmaceutical markets include	Singla Decl. Ex. M [Berndt, et al., "Network Effects And Diffusion In

therapeutic substitutes.	Pharmaceutical markets: Antiulcer Drugs," March 1999] at 3, 4 n.8. ("Pharmaceutical markets are usually bounded in terms of therapeutic classes of drugs, the members of which often are therapeutic substitutes.") (There are "many . . . examples of well-defined pharmaceutical markets . . . in which drugs all do much the same thing . . . in much the same way, and while their side effects and interactions differ somewhat, they are all therapeutic substitutes."). Singla Decl. Ex. P [Berndt, "Pharmaceuticals In U.S. Health Care: Determinants of Quantity and Price," *Journal of Economic Perspectives*, 16(4), Fall 2002] at 55 ("Market exclusivity for a certain brand of prescription pharmaceutical drug does not usually generate a pure monopoly situation, because most branded drugs face competition from other brands within a given therapeutic class. Within many therapeutic classes of drugs, a number of possible substitute medications exist, and in such cases, the market structure is more appropriately depicted by the differentiated product oligopoly framework.").
66. Cardura and generic doxazosin are as close substitutes for Hytrin as generic terazosin.	Singla Decl. Ex. Q [Soloway Depo.] at 49:21-50:18.
67. Cardura, in particular, is a very close substitute for Hytrin.	Singla Ex. Q [Soloway Depo.] at 11:7-8, 11:16-20, 16:13-20, 23:14-25, 53:12-19 ("[A]s far as efficacy, we would all agree that [Hytrin and Cardura are] equally effective as I indicated earlier in my testimony.").
68. In binding Rule 30(b)(6) testimony, Kaiser admitted that	Singla Decl. Ex. L [Millares Depo.] at 16:22-21:2, 96:15-97:23, 115:5-118:24.

doxazosin (Cardura) is a therapeutic alternative to Hytrin and that the products compete based on price.	
69. Kaiser and its expert allege that the relevant market here is limited to Hytrin and generic terazosin and excludes drugs such as Cardura, Minipress, and Flomax.	Singla Decl. Ex. D [Complaint] ¶ 95; Singla Decl. Ex. J [Berndt Report] ¶ 16.
70. Prof. Berndt did not believe the various alpha-blockers were "functional[ly] substitutab[le]" with Hytrin.	Singla Decl. Ex. O [Berndt Depo.] at 216:2-218:20.
71. Prof. Berndt is not an expert on whether various drugs are substitutable for each other.	Singla Decl. Ex. O [Berndt Depo.] at 218:22-219:16
72. Kaiser's expert Prof. Berndt admitted that if "an expert urologist came forward and said that, from his expert medical perspective, the alpha-blocker class was perfectly functionally substitutabil[e]" then Dr. Berndt would need to revisit his analysis, including conducting some form of formal econometric study.	Singla Decl. Ex. O [Berndt Depo.] at 220:9-221:9.
73. Kaiser's expert admitted that it would be "a reasonable way to proceed" to conduct an econometric price analysis to determine if Hytrin was in fact "perfectly functionally substitutable" with other alpha-blockers.	Singla Decl. Ex. O [Berndt Depo.] at 224:15-226:12.
74. Prof. Berndt did not use any econometric analysis here to exclude Cardura and other alpha-blockers from the alleged market.	Singla Decl. Ex. O [Berndt Depo.] at 15:24-18:5.
75. In each of the other cases in which Prof. Berndt has opined on pharmaceutical (or other) antitrust markets, he has conducted an	Singla Decl. Ex. O [Berndt Depo.] at 47:12- 48:14.

econometric analysis, such as analyzing cross-elasticities of demand to determine the degree to which different drugs compete with each other in the market.	
76. During pricing negotiations between Abbott and Kaiser over Hytrin, Kaiser threatened to switch to Cardura and Minipress if Abbott did not lower the price of Hytrin.	Singla Decl. Ex. T [9/18/03 Rosenshein Depo.] at 20:6-15, 20:20-23.
77. In the past, some Kaiser regions have switched between different alpha-blockers to treat BPH as a result of cost considerations.	Langenfeld Decl. Ex. B [March 15, 2004 Lagenfeld Report] at 80-82, 85.
78. Kaiser placed Hytrin on its formulary and thus purchased Hytrin instead of Cardura because of Hytrin's lower price.	Singla Decl. Ex. L [Millares Depo.] at 115:8-116:2.
79. At Kaiser, virtually all patients are given drugs on its formulary.	Singla Decl. Ex. D [Complaint] ¶ 18.
80. A third party insurance company viewed the various alpha-blockers — including Cardura, Flomax, Hytrin, and Minipress — as substitutable for each other and price-competitive.	Kroger Decl. Ex. A [Frear Depo.] at 71:8-18; 72:16-73:1; 74:10-16; 75:3-20; Kroger Decl. Ex. B [Edgar Depo.] at 96:6-97:13, 113:7-15.
81. Abbott viewed alpha-blockers as competitive, and created price and other incentives for managed care organizations to favor Hytrin over competing alpha-blockers.	Langenfeld Decl. Ex. A [March 22, 2002 Langenfeld Report] at 50-52; Singla Decl. Ex. S [Apr. 25, 2002 Langenfeld Depo.] at 39:1-11.
82. Hytrin's market share within the therapeutic class of alpha-blockers had been generally falling well before the entry of generic terazosin, starting with somewhat less than 50 percent in 1995, and dropping to about 30 percent in 1999.	Langenfeld Decl. Ex. A [March 22, 2002 Langenfeld Report] at 54 & Ex. 10.
83. Hytrin was losing share to	Langenfeld Decl. Ex. A [Langenfeld

generic Cardura and Flomax before entry of generic terazosin.	March 22, 2002 Report] at 54 & Ex. 10.
84. The negative impact of the generic Cardura entry on Hytrin sales was 66 percent that of generic terazosin.	Langenfeld Decl. Ex. A[March 22, 2002 Langenfeld Report] at 78.
85. The negative impact of the introduction of Flomax on Hytrin sales was 54 percent that of generic terazosin.	Langenfeld Decl. Ex. A [March 22, 2002 Langenfeld Report] at 78.
86. After the entry of generic terazosin with its lower price, there was a decline in sales of the sum of Hytrin and generic terazosin, reflecting at least in part competition from therapeutic alternatives.	Singla Decl. Ex. J [Berndt Report] at TAB 10.
87. Prof. Berndt relied entirely on the fact that Hytrin cost more than generic terazosin and that Abbott offered to sell Kaiser Hytrin tablets in August 1999 to meet the price offered to Kaiser for generic terazosin capsules.	*See generally* Singla Decl. Ex. J [Berndt Report] ¶¶ 16-26.
88. Tablets were an older dosage form; almost all of the rest of the market purchased capsules at this time.	Singla Decl. Ex. J [Berndt Report] ¶¶ 42-43.
89.Prof. Berndt stated that the fact that Hytrin was priced higher than generic terazosin (and that Abbott eventually offered to sell Hytrin tablets to Kaiser at the generic price) shows that Hytrin was priced at a "supra-competitive" level and, thus, Abbott must have a monopoly because only a monopolist can price at a supracompetitive level and, so, Hytrin must have been in a market by itself.	Singla Decl. Ex. J [Berndt Report] ¶¶ 64-65.
90. Prof. Berndt points to the settlements between Abbott and Geneva and Zenith as "proof" that Abbott made more money selling Hytrin than Abbott	Singla Decl. Ex. J [Berndt Report] ¶¶ 52-60.

and its generic competitors made selling Hytrin and generic terazosin.	
91. Abbott did not reduce output of Hytrin before generic entry. Rather output was higher in the supposed "monopoly" phase before generic entry.	Singla Decl. Ex. J [Berndt Report] ¶¶ 71-72.

2. **Brand Name Drugs Are Priced Higher Than Generics To Reflect Research And Development Costs.**

92. The pricing of Hytrin higher than its marginal or "short-run" cost does not show that the pricing is supra-competitive.	Singla Decl. Ex. O [Berndt Depo.] at 166:11-167:8; Singla Decl. Ex. O [Berndt Depo.] at 169:24-172:4 ("[E]ven though brand name pharmaceutical companies price their products much higher than short-run costs . . . that these companies aren't actually making more profits on a long-term basis than ordinary companies that price at the cost of production.").
93. If one accounts for the opportunity cost of capital from the sunk research and development costs of pharmaceuticals and then computes economic rates of return to brand name pharmaceutical companies, they are very similar to those obtained in other industries.	Singla Decl. Ex. O [Berndt Depo.] at 166:11-167:8, 170:14-17, 171:15-172:4.

3. **Kaiser Was A Formidable Negotiator That Could And Did Obtain Discounts Not Available To Others.**

94. Among health providers, Kaiser has a relatively unique approach to acquisition and dispensing of prescription drugs. Kaiser directly	Singla Decl. Ex. J [Berndt Report] ¶¶ 40, 40.1, 40.2.

purchases, warehouses, and dispenses drugs; and Kaiser negotiates contracts with drug companies on a national basis, taking advantage of the buying power associated with representing more than eight million patient lives.	
95. During the relevant period, Kaiser was a consumer of Hytrin.	Singla Decl. Ex. D [Complaint] ¶ 103.
96. During the relevant period, Kaiser was a formidable negotiator with drug manufacturers like Abbott.	Singla Decl. Ex. J [Berndt Report] ¶ 41; *see also* Singla Decl. Ex. O [Berndt Depo.] at 133:9-12 (during relevant period, Kaiser could force manufacturers to structure contracts with Kaiser differently than it did with most other purchasers. This included the ability to obtain discounts that were not generally available to most other managed care organizations.), 135:10-14 (Kaiser could "say to a potential seller… if you won't offer us the price that we think we can get from a competitor, we can move market share [to the competitor] very, very decisively."); Singla Decl. Ex. D [Complaint] ¶ 18 (During the relevant period, Kaiser had "the ability to negotiate favorable pricing in situations in which there is more than one drug for a particular therapeutic condition." And "Kaiser['s] ability to influence drug usage ('move market share' from the drug manufacturer's perspective) leads pharmaceutical companies to give Kaiser more favorable pric[ing] than other HMOs receive[d])."
97. Kaiser had Abbott specially manufacture tablets for Kaiser's use, and took steps to ensure that Kaiser pharmacists could fill a Hytrin prescription with tablets, regardless of the form in which the doctor prescribed Hytrin.	Singla Decl. Ex. J [Berndt Report] ¶¶ 42, 43.

98. In August 1999, prior to generic entry, Abbott was selling Hytrin tablets to Kaiser pursuant to large volume contracts for 70 cents per tablet. By contrast, Abbott was selling Hytrin capsules for the non-Kaiser patient population at significantly higher prices.	Singla Decl. Ex. J [Berndt Report] ¶ 44.2.
99. During the relevant period, Kaiser could shift virtually all of its utilization to a generic product within a very short period of time.	Singla Decl. Ex. D [Complaint] ¶ 21.
100. In August 1999, Kaiser entered into a contract with Geneva to purchase generic terazosin capsules for 20 cents per capsule from October 15, 1999 until February 15, 2000, and then for 10 cents per capsule from February 15, 2000 until December 31, 2003.	Singla Decl. Ex. J [Berndt Report] ¶ 82.
101. Kaiser's expert found that the price of Hytrin (sold only as capsules after Kaiser stopped buying tablets) remained "roughly stable" from pre- to post-generic entry.	Singla Decl. Ex. O [Berndt Depo.] at 267:3-24.

II. CONCLUSIONS OF LAW

A. KAISER'S WALKER PROCESS CLAIM DOES NOT RELATE BACK AND KAISER'S ASSERTED INJURY ENDED BY THE CRITICAL DATE, SO ABBOTT IS ENTITLED TO SUMMARY JUDGMENT

102. The critical date for Kaiser's *Walker Process* claim is October 27, 1999. 15 U.S.C. § 15b (providing 4-year statute of limitations for Sherman Act claims).	Singla Decl. Ex. H [Kaiser's "Bill of Particulars"] at 4-5.

103. Kaiser is not entitled to damages for the period after October 1, 1999, because by that point Kaiser was buying generic terazosin from Geneva instead of Hytrin from Abbott.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 187 (generic launched in August 1999); Singla Decl. Ex. J [Berndt Report] at Table 8, page 3 (showing that, beginning October 1, 1999, Kaiser's terazosin purchases were from Geneva not Abbott).
104. Kaiser has no valid claim for damages incurred after October 27, 1999, and any damages incurred before that date are time-barred, Abbott is therefore entitled to summary judgment.	
105. An amended pleading relates back only if it "asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B).	
106. Relation back is improper where the amended claim is "supported by facts that differ in both time and type from those the original pleading set forth." *Mayle v. Felix*, 545 U.S. 644, 650, 125 S. Ct. 2562, 2566, 162 L. Ed. 2d 582 (2005); *see also In re Markus*, 313 F.3d 1146, 1150-1151 (9th Cir. 2002) (Relation back is appropriate only "when the claim to be added will likely be proved by the same kind of evidence offered in support of the original pleadings.").	
107. In *Mayle*, the Supreme Court held an amended habeas petition alleging Fifth Amendment violations did not relate back to an earlier petition alleging a Sixth Amendment violation. *Mayle*, 545 U.S. at 665.	
108. In *Sierra Club v. Penfold*, 857 F.2d 1307 (9th Cir. 1988), the Ninth	

Circuit held that a challenge to the adoption of certain mining regulations did not relate back to an earlier complaint that had challenged the application of those same regulations by the same agency.	
109. "*Walker Process* antitrust liability is based on the knowing assertion of a patent procured by fraud on the PTO . . . . In contrast, [for sham litigation] . . . [i]t is the bringing of [a] lawsuit that is subjectively and objectively baseless that must be proved." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071-72 (Fed. Cir. 1998).	
110. Because the facts on which Kaiser's *Walker Process* claim relies were not included in Kaiser's original Complaint, the *Walker Process* claim does not relate back.	Singla Decl. Ex. D [Complaint]; Singla Decl. Ex. H [Kaiser's "Bill of Particulars"] at 4-5.

B. EVEN BASED ON KAISER'S ORIGINAL COMPLAINT, ITS *WALKER PROCESS* CLAIM IS TIME-BARRED.

111. A "limitations period commences when the plaintiff has a complete and present cause of action," which is when "the plaintiff can file suit and obtain relief." *Bay Area Laundry and Dry Cleaning Pension Trust Fund v. Ferbar Corp. of Cal., Inc.*, 522 U.S. 192, 201, 118 S. Ct. 542, 549, 139 L. Ed. 2d 553 (1997).	
112. "A civil cause of action under the antitrust laws arises [when] the plaintiff's interest is invaded to his damage, and the statute of limitations begins to run at that time." *Hennegan*	

v. Pacifico Creative Serv., Inc., 787 F.2d 1299, 1300 (9th Cir. 1986).	
113. Kaiser's allegation in its Complaint that, "[b]y 1996, generic manufacturers could and would have begun marketing a generic version of Hytrin but for Abbott's unlawful efforts to extend its patent monopoly" is a "judicial admission[]" that is "conclusively binding on" Kaiser. *Am. Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 226 (9th Cir. 1988).	Singla Decl. Ex. D [Complaint] ¶ 60.
114. Even if Kaiser's *Walker Process* claim related back to the date of its original Complaint, Kaiser's claim would still be time barred because, under Kaiser's own allegations, the conduct upon which Kaiser bases its claim and Kaiser's injury occurred more than four years before its Complaint, *i.e.*, before March 22, 1998, so Kaiser's claim accrued outside the limitations period.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 49 ('207 patent application filed in October 1994 and patent issued in April 1996), ¶ 109 (Abbott sued Geneva for infringement in June 1996), ¶ 112 (Abbott sued Novopharm for infringement in September 1996); Singla Decl. Ex. D [Complaint] ¶ 60 (Kaiser alleging that generic would have been on the market by 1996); Singla Decl. Ex. J [Berndt Report] ¶ 87.1 (Kaiser's expert calculating damages starting in 1996).
115. The antitrust laws do not recognize tolling for a plaintiff's alleged lack of actual or constructive knowledge of its claims. *Hennegan v. Pacifico Creative Service, Inc.*, 787 F.2d 1299, 1302 (9th Cir. 1986).	
116. Even if tolling were available, Kaiser had ample notice of its claims back in 1996.	Singla Decl. Ex. K [Kramer Depo.] at 78:18-80:4, 207:7-209:14 (acknowledging that Kaiser followed the litigation between Abbott and Geneva); Tabacci Decl. Ex. A [Geneva Answer] ¶¶ 33, 39, 41 (alleging same omissions in the '207 patent application upon which Kaiser now bases its Walker Process claim); C.F.R. § 1.11(a)

	(1996) (patent applications are publicly available once patent issues).
117. "A continuing violation is one in which the plaintiff's interests are repeatedly invaded and a cause of action arises each time the plaintiff is [resultingly] injured." *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 237 (9th Cir. 1987).	
118. In a continuing violation, a new distinct "*overt act* by the defendant is required to restart the statute of limitations and the statute runs from the last overt act." *Pace Industries, Inc. v. Three Phoenix Co.*, 813 F.2d 234, 237 (9th Cir. 1987) (emphasis added).	
119. A Section 2 claim based upon allegedly anti-competitive litigation accrues when the litigation is *filed* (and first causes injury); that the litigation continues into the limitation period does not cause the claim to accrue anew: "the initiation of judicial proceedings is the last overt act for purposes of the statute of limitations." *Pace Industries, Inc. v. Three Phoenix Co.*, 813 F.2d 234, 237-38 (9th Cir. 1987).	
120. The continuation of the patent infringement litigation continued into the limitations period would not save Kaiser's *Walker Process* claim from being time-barred, because according to Kaiser's own allegations, that claim accrued in 1996 when the litigation was filed and purportedly caused Kaiser injury.	Singla Decl. Ex. A [Joint Statement of Facts Not in Dispute] ¶ 49 ('207 patent application filed in October 1994 and patent issued in April 1996), ¶ 109 (Abbott sued Geneva for infringement in June 1996), ¶ 112 (Abbott sued Novopharm for infringement in September 1996); Singla Decl. Ex. D [Complaint] ¶ 60 (Kaiser alleging that generic would have been on the market by 1996); Singla Decl. Ex. J [Berndt Report] ¶ 87.1 (Kaiser's expert calculating damages starting in 1996).

121. Additional damage suffered in the limitations period does not cause a claim to re-accrue in the absence of a new anticompetitive overt act causing those damages. *Pace Industries, Inc. v. Three Phoenix Co.*, 813 F.2d 234, 241 (9th Cir. 1987); *In re Multidistrict Vehicle Air Pollution*, 591 F.2d 68, 71-72 (9th Cir. 1979); *David Orgell, Inc. v. Geary's Stores, Inc.*, 640 F.2d 936 (9th Cir. 1981).	
122. Kaiser's claim did not re-accrue simply because Kaiser continued to be unable to buy generic terazosin. *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 241 (9th Cir. 1987); *In re Multidistrict Vehicle Air Pollution*, 591 F.2d 68, 72 (9th Cir. 1979); *David Orgell, Inc. v. Geary's Stores, Inc.*, 640 F.2d 936 (9th Cir. 1981).	
123. If a claim is not filed within four years of when it accrued, the entire claim is time-barred regardless of how long damages continued thereafter. *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 241 (9th Cir. 1987).	
124. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), "conflict[s] with numerous decisions of other circuits"—including the Ninth Circuit—which limit the continuing violation doctrine to acts "sufficiently independent of the initial unlawful act." II Areeda & Hovenkamp, Antitrust Law ¶ 320c4 at 302.	
125. "[C]ourts consistently hold that if the monopoly is created by a single identifiable act . . . , the statute of limitation runs from the time of	

commission of the act, notwithstanding that high prices may last indefinitely into the future." II Areeda & Hovenkamp, Antitrust Law ¶ 320c4 at 298-99.	

C. KAISER LACKS ANTITRUST STANDING.

126. "Congress did not intend to provide a private remedy for all injuries that might conceivably be traced to an antitrust violation." *Bubar v. Ampco Foods, Inc.*, 752 F.2d 445, 448 (9th Cir. 1985).	
127. Beyond ensuring that plaintiffs have met the requirements for Article III standing, courts in antitrust cases "must make a further determination whether the plaintiff is a proper party to bring a private antitrust action." *Associated General Contractors of Cal., Inc. v. California State Council of Carpenters*, 459 U.S. 519, 535 n. 31, 103 S. Ct. 897, 907, 74 L. Ed. 2d 723 (1983) ("*AGC*"). "[C]ourts should analyze each situation in light of the policy factors" the Supreme Court set out in *AGC*, including "the directness of the injury." *Bubar v. Ampco Foods, Inc.*, 752 F.2d 445, 449 (9th Cir. 1985).	
128. Courts that have considered the antitrust standing requirements for *Walker Process* claims in the Hatch-Waxman context have consistently held that only competitors or parties sued or threatened with a patent infringement suit have antitrust standing. *See In re Remeron Antitrust Litigation*, 335 F. Supp. 2d 522, 529 (D.N.J. 2004) (direct purchaser lacked standing); *In re DDAVP Direct & Indirect Purchaser*	

Antitrust Litig., 2006 US DIST LEXIS 96201 (S.D.N.Y. 2006) (same); *In re K-Dur Antitrust Litig.*, 2007 WL 5297755, at *17-18 (D.N.J. Mar. 1, 2007) (indirect purchasers lacked standing); *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) (Posner, J. by designation) (in the Hatch-Waxman context, holding *Walker Process* standing is limited to competitors); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 547 (E.D.N.Y. 2005) (stating, in the Hatch-Waxman context, that "there is a serious question whether [purchaser] plaintiffs have standing to assert a *Walker Process* claim").	
129. The original defendants in the underlying patent litigation—including Geneva and Novopharm here—are the ones who would have been directly injured and the ones best placed to evaluate whether Abbott's patent prosecution had any anticompetitive effect. They are an "identifiable class of 'persons' whose self-interest would normally motivate them to vindicate the public interest," and their presence makes purchaser standing unnecessary. *In re K-Dur Antitrust Litigation*, 2007 WL 5297755, *17-18 (D.N.J. Mar. 1, 2007) (quoting *AGC*, 459 U.S. at 542).	
130. "Under the typical *Walker Process* scenario, the patentee seeks to exclude other producers who make, or hope to make, products that compete with the patented product. . . . [The purchasers] are only 'indirect' victims of the anticompetitive behavior." Robert G. Badal, *et al.*, *Speculation, Overdeterrence, and Consumer*	

Standing in Walker Process Litig., 13 Sw. J.L. & Trade Am. 325, 328 (2007).	
131. The contingent nature of any injury to purchaser plaintiffs is magnified in the Hatch-Waxman pharmaceutical context where a generic's ability to enter the market depends on many regulatory requirements. *See* 21 C.F.R. Parts 210 and 211.	
132. Kaiser lacks antitrust standing here.	

D. KAISER'S CLAIM FAILS AS A MATTER OF LAW FOR LACK OF EVIDENCE OF MONOPOLY POWER IN A RELEVANT MARKET

133. Section 2 imposes its harsh mandatory treble damages remedy only where a defendant's predatory conduct has resulted in its monopolization of "any part of the trade or commerce among the several States." 15 U.S.C. § 2.	
134. The Supreme Court has consistently interpreted 15 U.S.C. § 2 to require a plaintiff to prove monopoly power "in the relevant market." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S. Ct. 1698, 1703-04, 16 L. Ed. 2d 778 (1966).	
135. "Under Section 2 of the Sherman Act, identification of the relevant market is *essential* to proving monopolization or attempted monopolization." ABA Section of Antitrust Law, Antitrust Law Developments (5th ed. 2002) at 528 (emphasis added); *accord* 1 Irving Scher, Antitrust Adviser § 1.22 (4th ed.	

2003) ("Antitrust Adviser"); 2 Areeda & Hovenkamp, Antitrust Law ¶ 531c, at 189 (2d ed. 2002) ("Areeda vol. 2").	
136. "Without a definition of that market there is no way to measure [the defendant's] ability to lessen or destroy competition." *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177-78, 86 S. Ct. 347, 350, 15 L. Ed. 2d 247 (1965).	
137. With respect to the offense of attempted monopolization, "it is beyond dispute that [the offense of monopolization] requires proof of market power in a relevant market." *Spectrum Sports, Inc. v. McQuilan*, 506 U.S. 447, 457, 459 (1993).	
138. Under controlling Ninth Circuit law, "defining the relevant market is indispensible to a monopolization claim." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1373-74 (9th Cir. 1989); *accord Oahu Gas Service, Inc. v. Pacific Resources Inc.*, 838 F.2d 360, (9th Cir. 1988) (Section 2 requires "the possession of monopoly power in the relevant market").	
139. "[Section] 2 makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so." *Spectrum Sports v. McQuillan*, 506 U.S. 447, 459, 113 S. Ct. 884, 892, 122 L. Ed. 2d 247 (1993).	
140. Summary judgment is appropriate where the plaintiff's proposed market excludes potentially competing products. *See, e.g., Morgan, Strand, Wheeler & Biggs v. Radiology,*	

Ltd., 924 F.2d 1484, 1489-90 (9th Cir. 1991) (affirming summary judgment because plaintiff's proposed market of private medical radiologists implausibly excluded potential competitors such as university and osteopathic radiologists as well as radiological services from non-radiologist physicians); *Thurman Indus.*, 875 F.2d at 1377 (affirming summary judgment because plaintiff's proposed market for home center stores ignored potential competition from other classes of retailers).	
141. "In considering what is the relevant market for determining the control of price and competition, no more definite rule can be declared than that commodities reasonably interchangeable by consumers for the same purposes make up that 'part of the trade or commerce,' monopolization of which may be illegal." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395, 76 S. Ct. 994, 1007, 100 L. Ed. 1264 (1956).	
142. "[I]f consumers view the products as substitutes, the products are part of the same market." *Rebel Oil*, 51 F.3d at 1435; *see also Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1374 (9th Cir. 1989) (relevant market defined based upon "reasonable interchangeability of use and cross-elasticity of demand").	
143. The Supreme Court has specifically warned against market definitions limited to a single manufacturer or a single product among differentiated products. *Du Pont*, 351 U.S. at 393.	

144. "Courts have consistently held that a brand name product cannot define a relevant market." *Mathias v. Daily News, LP*, 152 F. Supp. 2d 465, 479-80, 482 (S.D.N.Y. 2001); *see also Green Country Food Mkt., Inc. v. Bottling Group, LLC*, 371 F.3d 1275, 1282 (10th Cir. 2004) ("[C]ourts reject the argument that a single branded product constitutes a relevant market."); *Domed Stadium Hotel, Inc. v. Holiday Inns, Inc.*, 732 F.2d 480, 488 (5th Cir. 1984) ("[A]bsent exceptional market conditions, one brand in a market of competing brands cannot constitute a relevant product market.").	
145. "[T]he few cases in which courts have acknowledged the possibility of limiting the relevant market to a single brand have involved markets for replacement parts for specific brands of durable goods where consumers are 'locked -in' to maintaining them." *Streamcast Networks, Inc. v. Skype Technologies, S.A.*, 547 F. Supp. 2d 1086, 1094-95 (C.D. Cal. 2007) (collecting cases).	
146. Kaiser's proposed market definition fails because it excludes drugs that are reasonably interchangeable with Hytrin.	
147. That the price of Hytrin was higher than the price of generic terazosin does not demonstrate that Abbott had monopoly power. *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675. 681 (D.N.J. 2005) (holding that price differential between brand name drug and generic did not show that brand name drug had	

a monopoly).	
148. To show directly that Abbott was exercising monopoly power, Kaiser would need evidence not only of supra-competitive prices but also of reduced output. *See, e.g.*, *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) (rejecting finding of monopoly power based upon evidence that defendant hospital "routinely charged higher prices than other hospitals while reaping high profits" because plaintiff made no showing of restricted output).	
149. The meeting or beating a discounter's price to a bulk purchaser is not evidence of monopoly power.	

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